



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/537,732

06/07/2005

Steven W Sutton

JJPR-0177

6621

23377 7590 01/23/2009
WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

EXAMINER

WEGERT, SANDRA L

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

01/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,732	SUTTON ET AL.	
	Examiner	Art Unit	
	SANDRA WEGERT	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-11 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and Claims:

Applicants' Remarks, submitted 9 September 2008, have been entered and considered.

Claims 12-21 have been cancelled (11 March 2008).

Claims 1-11 are under examination in the current application.

Withdrawn Rejections

Claim Rejections - 35 USC § 112, first paragraph-Enablement

The rejection of claims 1-11, under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn based on applicants' arguments (9 September 2009) that a DNA or mRNA microarray was performed that identified an orexin-2 receptor in the PFSK-1 cells used for the claimed method (referring to the Specification at p. 9).

New Rejections

Claim Rejections- 35 USC § 102

The following are quotations of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1647

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8, 10 and 11 are rejected under 35 U.S.C. 102(b) as being unpatentable over Sakurai, et al, 1998 (Cell, 92: 573-585, of record). Sakurai, et al identified and performed experiments with several orexin peptides and orexin receptors (see Abstract and Introduction). They identified and sequenced three orexin peptides and four orexin receptors (Figure 2). They performed binding assays on CHO and HEK-293 cells comprising the receptors, as well as tested orexin responses of hypothalamic neurons in rats (Figure 3 and p. 579, last paragraph). In all experiments, the researchers applied the ligands to the outside of intact cells, showing that the receptors occur in the cell membranes- and therefore presumably also in membrane fragments. Not surprisingly, using immunohistochemical staining of sliced brain tissue, Sakurai, et al also identified the receptor in cytoplasmic compartments (p. 579, second column) showing that it is synthesized through the usual pathways from endoplasmic reticulum to Golgi lamellae and then inserted into the plasma membrane. The researchers performed binding assays on the receptors, including competitive binding assays (Figure 3, parts A and B). They also measured the rise in the intracellular second messenger calcium (Figure 3, parts C and D). The binding assays in Sakurai, et al demonstrate that the orexins are agonists at their specific receptors (e.g., OX₁ or OX₂) and are partial antagonists at the "wrong" receptor when competitively combined with the "correct" orexin agonist (Figures 3 and 6). From the data presented in Sakurai, et al, there does not seem to be evidence that the orexin receptors are constitutively hyperpolarized, such that it would be possible to use an inverse agonist (as recited in claim 11). The paper by Sakurai, et al meets the limitations of claim 1 and dependent claims of a method of identifying ligands of the

Art Unit: 1647

"orexin-2" receptor where the orexin receptor is specified by name only and not by SEQ ID NO.

It is noted that the specification does not define the term "orexin-2 receptor" as being limited to a particular structure. Sakurai, et al identified and sequenced at least two receptors that they named "orexin-2" (Figure 2C).

Claim Rejections-35 USC § 103(a), Obviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurai, et al, 1998 (Cell, 92: 573-585, discussed above) in view of Huang, et al, (1997, Proc. Natl. Acad. Sci., 94: 6159-6163).

As discussed above, Sakurai, et al teach a method of identifying compounds that modulate human orexin-2 receptor activity comprising testing compounds in binding assays on CHO and HEK-293 cells comprising the receptors. Sakurai, et al measured the second messenger calcium to measure the effect of the tested compound.

Sakurai, et al do not teach using cells transfected with a G α -protein DNA construct. However, such transformed cells were known in the art as being useful in binding assays. For example, Huang, et al teach transfection of several cell types with exogenous G α -protein genes

Art Unit: 1647

(keeping in mind that all the G-proteins listed are species of $G\alpha$ proteins) and demonstrates subsequently that the G-proteins interact promiscuously with endogenous receptors.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to identify compounds that interact with an orexin-2 receptor using cells possessing the orexin-2 receptor, as well as possessing (either endogenously or exogenously) the appropriate intracellular messenger proteins that could transduce a detectable response. The skilled artisan would be motivated to do so because Sakurai, et al demonstrated that Orexin receptors mediate satiety signals in the brains of mammals (p. 579). There would be a reasonable expectation of success, since assaying orexin receptors using binding techniques has been well-established, and exogenously transfecting cells with $G\alpha$ -proteins results in functional $G\alpha$ -proteins, even if the G-proteins were foreign in origin, as evidenced by Huang, et al. Combining the teachings of these references would have been obvious since known work in one field of endeavor was well known to prompt variations of it in the same field based on design incentives as long as the results would have been predictable, as was the case in this instance.

Claim Objections

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1-3 and 5-11 are rejected. Claim 4 is objected to.

Art Unit: 1647

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Manjunath Rao, can be reached at (571) 272-0939.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

SLW

8 January 2009

/Elizabeth C. Kemmerer/

Elizabeth C. Kemmerer, Ph.D.
Primary Examiner, Art Unit 1646